Virtual Ports
Laparoscopy Systems

Virtual Ports Ltd.

510(K) SUMMARY

MAR 21 2008

510(k) Number K 080051

Applicant's Name: Virtual Ports
Teradion Industrial Park
6 Kahol Street
D.N Misgav 20179
ISRAEL
Tel: (972)4-999-0189
Fax: (972)4-999-1901

Contact Person: Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: *EndoClear*™ system
Common name: Accessory to a Laparoscope

Classification:
Name: Endoscope and accessories
Product Code: GCJ
Regulation No: 876.1500
Class: II
Classification Panel: General and Plastic Surgery

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

1. Laparoscope and Monopolar laparoscopic instruments; Instrumed International, Inc. K040855.
2. g-Lix™ Tissue Grasper; USGI Medical K061268

Device Description:

The Virtual Ports EndoClear™ system is a sterile, single patient use system consisting of: EndoClear™ Lens Cleaner and the EndoClear™ Introducer. The EndoClear™ Lens Cleaner is an internally anchored, hands-free, laparoscope lens cleaning device which is attached to the internal abdominal cavity wall and remains in position until

completion of the surgery, enabling the surgeon to effectively clean the lens of blood, fat, fog, and secretions without removing it from the cavity.

The Virtual Ports EndoClear™ Lens Cleaner is introduced via a cannula using the EndoClear™ Introducer, which also removes the EndoClear™ Lens Cleaner at the end of the surgical procedure.

Intended Use Statement:

EndoClear™ Laparoscopes Accessory is intended to be used by qualified physicians to provide endoscope lens cleaning for uninterrupted visualization of internal structures in a wide variety of diagnostic and therapeutic laparoscopic procedures.

Performance Validation:
Performance Testing – bench tests

Series of bench tests were performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

Performance Testing - animal

An animal study was performed in order to evaluate the safety and effectiveness of using the Virtual Ports EndoClear™ System as an internal endoscope lens cleaner. This study demonstrated that the EndoClear™ system performs as intended and that no safety and effectiveness questions were raised.

Tests conclusion:

Both bench tests and the animal study were shown that the device performs safely and efficiently in accordance with its intended use.

Materials:

Materials of the *EndoClear* ™ device that are in contact with the human body are biocompatible in accordance with ISO 10993-1.

Substantial Equivalence:

Preclinical and bench performance data was supplied to demonstrate that the *EndoClear* ™ meets its labeled performance claims, and to demonstrate substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2008

Virtual Ports
% Qsite
Yoram Levy
General Manager
31 Haavoda Street
Binyamina, Israel

Re: K080051
Trade/Device Name: EndoClear™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 5, 2008
Received: March 10, 2008

Dear Yoram Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Virtual Ports
Laparoscopy Systems

Virtual Ports Ltd.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: EndoClear™ System

Indications for Use:

EndoClear™ Laparoscopes Accessory is intended to be used by qualified physicians to provide endoscope lens cleaning for uninterrupted visualization of internal structures in a wide variety of diagnostic and therapeutic laparoscopic procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	x	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)		

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Division of General, Restorative and Neurological Devices

510(k) Number

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080051